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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,779	09/23/2004	Yoshihiko Masaki	40072-0011	8473

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,779	MASAKI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Nathan Schlientz can be reached at 571-272-9924.

Status of Claims

Claim 10 has been amended and Claims 12-17 have been cancelled by amendment filed 28 February 2007. As a result, Claims 1-4 and 6-11 are pending and examined herein on the merits for patentability. No claim is allowed at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 3, 4 and 6-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284 (hereinafter the Takama '284 publication).

With respect to Claims 1, 3, 4 and 6-11 of the instant application, the Wada '801 publication teaches an organ transplant preservation perfusion solution for preserving organ function, a method of using said organ transplant preservation perfusion solution to preserve organs, and a method of making said organ transplant preservation perfusion solution, wherein said organ transplant preservation perfusion solution comprises: starch present at a concentration from 0 g/L to 80 g/L; sodium cation present at a concentration' from 10 mM to 140 mM; potassium cation present at a concentration from 4 mM to 140 mM; magnesium cation present at a concentration from 0 mM to 4 mM; calcium cation present at a concentration from 0 mM to 2 mM; dihydrogen phosphate anion or hydrogen phosphate anion present at a concentration from 12 mM to 65 mM; and at least one component present at a concentration from 15 mM to 150 mM and selected from the group consisting of: chloride anion; hydrogen carbonate anion; carbonate anion; organic acids; and organic anions; wherein said organ may include a lung (page 5, [0001] and [0003]; page 6, [0005]; page 7, [0006]-[0008]; page 9, [0016]; claim 1).

Although the Wada '801 publication teaches utilizing starch present at a concentration from 0 g/L to 80 g/L within said organ transplant preservation perfusion Solution, the Wada '801 publication does not explicitly teach utilizing an inulin fructan

oligosaccharide within said organ transplant preservation perfusion solution, as instantly claimed.

However, the Takama '284 publication teaches a preservation solution for preserving live cells (page 5, [constitution]; claims 1 and 2), a method of using said preservation solution to preserve live cells (claim 1), and a method of making said preservation solution (page 7, [0007]; page 10, [0011]), wherein said preservation solution for preserving live cells comprises: (1) a 1-ketose inulin fructan oligosaccharide (page 8, [0010]; page 9, [0010]; claims 1 and 2) and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides (page 10, [0011]); and (2) an optional additional preservation solution (page 5, [constitution]; page 10, [0012]; page 19, [0030]).

Although the Takama '284 publication teaches a preservation solution for preserving live cells comprising: (1) a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides; and (2) an optional additional preservation solution, the Takama '284 publication does not explicitly teach specific ingredients comprising said optional additional preservation solution and that said preservation solution is useful for preserving not only live cells, but also organs, as instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute for the starch ingredient present within the organ transplant preservation perfusion solution of the Wada '801 publication, a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides, since not only is starch a polymer of glucose sugars, but also

1-ketose and nystose inulin fructan oligosaccharides are likewise polymers of glucose sugars, as well as fructose sugars, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides within the preservation solution of the Takama '284 publication, for the starch ingredient within the organ transplant preservation perfusion solution of the Wada '801 publication, since a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides are also useful for preserving live cells, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

2. Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284 (hereinafter the Takama '284 publication) and in further view of Japanese Patent Application Publication 07-099965 (hereinafter the Matsumoto '965 publication).

The teachings of the Wada '801 publication and the Takama '284 publication are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to Claim 2 of the instant application, neither the Wada '801 publication, nor the Takama '284 publication explicitly teach a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides having a specific degree of polymerization from 3 to 6, as instantly claimed.

However, the Matsumoto '965 publication teaches a composition for protecting live cells from frost damage comprising: (1) an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6 (page 10, [0011]; page 14, [0019]; page 15, [0021]; claims 2, 3, 6 and 7); and (2) an optional additional preservation composition (page 9, [0008], [0010], [0011]); wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4 (page 6, [0001]; page 7, [0003]; page 8, [0005]-[0006]; page 9, [0008], [0010], [0011]; page 10, [0011]-[0012]; page 11, [0013]; page 14, [0019]; page 15, [0021]; page 19, [0028]; Claims: 1-7).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to incorporate for the 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides present within the organ transplant preservation perfusion solution of the Wada '801 publication, an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6;

wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4, which is/are present within said composition for protecting live cells from frost damage, as reasonably suggested by the Matsumoto '965 publication.

One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4, which is/are present within said composition for protecting live cells from frost damage, as reasonably suggested by the Matsumoto '965 publication, for the 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides present within the organ transplant preservation perfusion solution of the Wada '801 publication, since the Matsumoto '965 publication reasonably suggests that said composition is particularly useful for protecting live cells from frost damage, wherein said composition comprises: an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization, of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more

inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

Response to Arguments

Applicant's arguments filed in a Response on 28 February 2007 have been fully considered but they are not persuasive.

Applicants' argue on page 7 of the aforementioned Response that although many polymers of sugars were known, one could not predict which would have been effective for preserving organs. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner combines the teachings of Wada '801 and Takama '284 for the suggested use of 1-kestose and nystose inulin fructan oligosaccharides in the composition of Wada '801.

3. Applicants' argue on page 7 of the aforementioned Response that although it was possible to preserve cells through freezing, it was not possible to preserve organs by freezing and it was well-known that organs could not be preserved for as long as cells. However, Wang et al. disclose freezing an isolated rat heart at –1.2 and –3 °C,

wherein the heart flushed with 0.15 mM $CaCl_2$ rendered good functional return (Cryobiology, 1991, 28(2), Abstract). Also, In response to applicant's argument that it was well-known that organs could not be preserved for as long as cells, it is noted that the length of preservation is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

This is a Request for Continued Examination of Applicant's Application No. 10/508,779. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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